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ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/899,372	VAN DYKE ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-65 and 67-96i* is/are pending in the application.

4a) Of the above claim(s) *69-92 and 94-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55-65, 67, 68 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' request for reconsideration filed 09/29/2008.

Claims 55-65, 67-93 are pending.

Claims 69-92, 94-96 are withdrawn as being directed to a nonelected invention. Election was made without traverse in Paper filed 02/28/2002.

Claims 55-65, 67, 68 and 93 are included in the prosecution.

The following rejections have been discussed in details in the previous office action, and are maintained for reasons of record:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 55-56, 67, and 68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for topical composition comprising water

soluble peptides, does not reasonably provide enablement for compositions other than topical, i.e. oral or parentral. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir.1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is composition comprising soluble peptides.

The breadth of the claims: The claims are broad. The claims encompass all the possible formulations or compositions including parentral.

The state of the prior art: The state of the art recognized peptides administered topically to treat wounds, US 5,932,552.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on composition comprising water soluble

peptides that is administered by any route other than topical administration for wound treatment or as cell scaffold. It is not obvious from the disclosure of topical composition comprising peptides if any other composition comprising peptide will work in terms of wound treatment. On page 5, lines 10-17, applicants disclose that peptide is placed over the wound as powder, or formulated into cream, gel, or cast the peptide powder onto polymer or keratin dressing. On page 9, lines 8-19, applicants disclose the peptide used for growth of keratinous tissue, treating external wound, or treating aging skin, and all are achieved by admixing the peptide with a cream, lotion, or gel. Therefore, applicants' disclosure supports topical formulations acting topically, and does not support any other formulation that may act systemically and provide topical action on the skin. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the formulations fall within the scope of a claim will possess the alleged activity.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to composition comprising soluble peptides used for treating wound or tissue scaffold that is administered by any other route than topically makes practicing the claimed invention unpredictable in the terms of other forms of what composition administered non-topically and still suitable as wound dressing or tissue scaffolding.

The presence or absence of working examples: The specification discloses topical composition for treating wounds. No working examples to show other

compositions such as parentral that acts topically. Therefore, the specification has enabled only topical compositions.

The quantity of experimentation necessary: The practitioner would turn to trial and error experimentation to practice the instant composition for treating wound, tissue scaffold or for implantation using non-topical composition without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

Response to Arguments

3. Applicant's arguments filed 09/29/2008 in the brief have been fully considered but they are not persuasive.

Applicants argue that the Examiner's rejection of the claims for lack of enablement is based on the erroneous concept that the claimed material must be used only for topical therapeutic formulations. Although the Specification describes therapeutic formulations that may be made with the claimed composition, including topical formulations, the claimed composition is not limited to those described formulations. Applicants argue that if any use is enabled when multiple uses are disclosed, the application is enabling for the invention. The Specification discloses many uses for the composition that are known in the art and would not require undue experimentation. The Specification enables one of skill in the art to manufacture and use the claimed composition in a formulation for topical administration via a cream, lotion, gel, hydrogel, or wound dressing to a human or animal subject, and the

Specification provides more uses that are broader than topical application. Specification says "the peptide can be used to promote healing, repair, and cell growth in keratinous tissue generally." The Specification states that “the peptide can be applied internally to damaged keratinous tissue lining the GI tract by orally administering the peptide." The composition could also be used as a nutritional supplement. No burden of showing undue experimentation has been shown. Applicants argue that peptides are known to given orally. Applicants further argue that the issue is not whether the specification enables all possible uses of the peptides, but rather, the enablement of the peptide composition independent of adding it to a particular carrier.

In response to these arguments, it is argued that the specification has enabled how to make the peptide composition and how to use it topically to stimulate growth of useful cell types, and has not enabled any uses other than topically for stimulating wound healing and cell growth. The peptide of the present invention is used to promote healing, repair, and cell growth in keratinous tissue, page 10, lines 1-13 of the present specification. In the same paragraph, applicants disclosed using the peptide to treat the keratinous tissue lining GIT by oral administration of the peptide composition. Therefore, the peptide composition of the present invention is acting only locally to the site of application on the keratinous tissue. Even if the formulation administered orally it is disclosed to act locally on the GIT lining, i.e. keratinous tissue. No systemic effect has been disclosed by the present composition. The Specification enables one of skill in the art to manufacture and use the claimed composition in a formulation for topical

administration via a cream, lotion, gel, hydrogel, or wound dressing to a human or animal subject, which all are topical formulation for topical/local administration to act locally at the site of application. On page 5, lines 10-17, applicants disclose that peptide is placed over the wound as powder, or formulated into cream, gel, or cast the peptide powder onto polymer or keratin dressing. On page 9, lines 8-19, applicants disclose the peptide used for growth of keratinous tissue, treating external wound, or treating aging skin, and all are achieved by admixing the peptide with a cream, lotion, or gel. The disclosed composition is intended to be applied to the damaged keratinous tissues either skin or mucosa of GIT, and not intended to be administered systemically as encompassed by the scope of the claims. Therefore, the specification has only enabled how to make and how to use topical composition comprising soluble peptides applied to the keratinous tissues using topical formulations and providing local topical effect at the site of application.

Contrary to applicants' allegation that nutritional supplement is disclosed, with careful recourse to the specification, no disclosure of nutritional supplement.

It is further argued that the focus of the examination inquiry is whether everything within the scope of the claim is enabled. Instant claims encompass all formulations of peptides administered by all the routes of delivery that is not topical to induce topical effect. Therefore, applicants are in possession to topical formulation that acts locally, and not to all formulations including oral, parentral, and all other non-topical formulations.

Applicants argue that if any use is enabled when multiple uses are disclosed, the application is enabling for the invention, however, in the present specification no multiple uses are disclosed, only topical use is disclosed, therefore, application is not enabling for the invention as claimed.

Accordingly, it is the examiner's duty to determine exactly what subject matter is encompassed by the claims. See, *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir.2003). The present claims encompass topical formulation and topical delivery as disclosed by the specification. Nowhere applicants have disclosed any formulations other than topical to act locally, as set forth, because it is not clear from the disclosure that the peptide formulation can be formulated in an oral formulation, for example, and still provides healing and growth to the keratinous tissues or still be capable to work as tissue scaffold.

Additionally, the claims are broad, and the examiner's concern is that the scope of enablement provided to one skilled in the art by the disclosure is not commensurate with the scope of protection sought by the claims. Applicants did not show possession of the invention as instantly claimed with all its limitations, encompassing all formulations, by any means of descriptive words, structure, figures, or diagrams. The specification has thus not met the requirements of first paragraph of 35 USC 112, which states that: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention".

It is further argued that the Federal Circuit has repeatedly held that "the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed.Cir. 1993). As set forth, the present claims encompass topical formulation and topical delivery as disclosed by the specification. Nowhere applicants have disclosed any formulations other than topical to act locally, and it is not clear from the disclosure that the peptide formulation can be formulated in an oral formulation, for example, and still provides wound dressing or tissue scaffold. The burden is on the examiner to unduly experiment all possible oral formulations, parentral formulations and implantable formulations, etc, and their capability to treat wounds and enhance growth of keratinous tissue when applied non-topically. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the formulations fall within the scope of a claim will possess the alleged activity, and this is what is missing from the present disclosure

Regarding the argument concerning the "undue experimentation", it is argued that a conclusion of lack of enablement means that, based on the evidence regarding each of the "*In re Wand"* factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright,* 999 F.2d 1557, 1562, 27

USPQ2d 1510, 1513 (Fed. Cir. 1993).The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. These factual considerations are discussed more fully in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

In response to applicants' argument that peptides are know to be given orally, and the specification enabled peptides independent of adding it to any carrier, it is argued that the issue is not if peptides were known at the time of the invention or if were known to be given orally or not, the issue is were applicant in possession of the claimed subject matter or not? At the time of the invention, applicants were not in possession of all routes of administration of peptide to achieve topical effects.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 55-65, 67, 68 and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,276,138 ('138).

The present claim 55 is directed to product by process, the product is directed to composition comprising water soluble peptide.

US '138 disclosed a solubilized keratin powder from animal hair or wool (abstract; col.2, lines 65-67). The method of production of the keratin included the steps of oxidation of wool solution by hydrogen peroxide or peracetic acid (col.3, lines 3-5, 21-24), neutralization (col.5, lines 67-68), filtration (col.5, lines17-21), precipitation of a powder (col.4, lines 20-28; col.6, line 5), and washing the filtrate with solvent such as acetone, methanol or ethanol (col.6, lines 1-5). The reference further disclosed the step of drying the washed precipitate (col.5, lines 30-31). Further see example 1 for the method steps. The powder is used in cosmetics (col.4, lines 22-23). US '138 at col.5, lines 22-25, and figure 1 disclosed that low molecular weight peptides are also produced. The methods of peptides separation and isolation according to their molecular weights are known in the art including different chromatography techniques, different electrophoresis techniques, and ultracentrifugation, as evident by "BIOCHEMISTERY" book by Voet et al., pages 75-107 (provided). According to the intended use of the peptide, the desired molecular weight would have been filtered and separated from the soluble peptides pool disclosed by US '138.

Regarding the limitation of claim 55 that "90% of the water soluble peptide are between 300 and about 1300 Dalton in molecular weight", this limitation is referring to the soluble peptides precipitated during the process of production, and it is not clear

from the claim if the peptide included in the claimed composition are chosen from the 90% fraction having the molecular weight between 300 and 1300 Dalton, or chosen from the 10% having other molecular weights! This 90% fraction of soluble peptides having 300-1300 Dalton molecular weight is not claimed as the soluble peptides included in the claimed composition. Further, claim 55 recites "the precipitate comprises water soluble peptide", and with this "comprising" recitation it is difficult to determine which fraction of peptide included in the claimed composition? Is it the 90% fraction having 300-1300 molecular weight or is it the 10% fraction having other molecular weights?

Additionally, the instant claims are directed to product by process, and all the elements of the claimed product are disclosed by US '138, which is composition comprising soluble peptide. The peptide disclosed by US '138 is soluble and used for cosmetics as desired by applicants. Therefore, the present product is identical of the product of US '138 and capable of functioning in the same way as a cosmetic. Therefore, claimed product by process is anticipated by US '138 because even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is anticipated even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985). Since US '138 product is identical to the present claims, i.e. composition comprising water soluble peptide, the burden is shifted to

applicants to show an obvious difference to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596(CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Moreover, the instant specification fails to set forth any specific method by which the claimed peptides are obtained. Rather it provides a panoply of generalized conditions which embrace the teachings of the '138 patent. Therefore, absent a specific method which results in the claimed peptides it is anticipated that any method falling within the general teachings of applicant's specification will yield the claimed peptides.

Response to Arguments

6. Applicant's arguments filed 09/29/2008 have been fully considered but they are not persuasive.

A. applicants argue that the scope and content of the '138 reference do not in include or suggest all the elements of the present claims. Applicants argue that the present invention is based on the surprising result that the filtrate of oxidized hair contains biologically active peptides that can be collected by neutralizing the filtrate and precipitating out the peptides with a water-miscible organic solvent. US '138 teaches discarding the filtrate of oxidized hair and using the precipitate to recover much larger molecular weight proteins. Thus, the '138 patent contains no description or suggestion of the present invention.

In response to this argument, applicants' attention is directed to the scope of the present claims that are directed to composition comprising soluble peptide, and the reference discloses water soluble peptides as instantly claimed. Applicants themselves admit that the reference disclosed all the steps of the claimed method. It is further argued that US '138 at col.5, lines 22-25, and figure 1 disclosed that low molecular weight peptides are produced. Since US '138 product is identical to the present claims, i.e. composition comprising water soluble peptide, the burden is shifted to applicants to show an obvious difference to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596(CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Moreover, the instant specification fails to set forth any specific method by which the claimed peptides are obtained. Rather it provides a panoply of generalized conditions which embrace the teachings of the '138 patent. Therefore, absent a specific method which results in the claimed peptides it is anticipated that any method falling within the general teachings of applicant's specification will yield the claimed peptides.

B. Applicants argue that US '138 describes a different process for obtaining the peptides. US '138 teaches a process by oxidizing the hair, filtering it through a mesh (discarding the filtrate), precipitating with an acetic acid, filtering through a filter paper (discarding the filtrate), washing, drying, and pulverizing to obtain a powder. The present disclosure, on the other hand, teaches a different process; oxidizing the hair,

filtering it (retaining the filtrate to collect the low molecular weight, water-soluble peptides), neutralizing the filtrate with a base, precipitating out the water-soluble peptides by mixing with a water- miscible organic solvent, filtering again and evaporating the precipitate. Thus, the '138 reference teaches one skilled in the art to discard the objects of the present composition claims by disposing of the filtrate in the first filtration step. The '138 process contains no description of the water-soluble peptides found in the filtrate of the oxidized hair. The present disclosure is not obvious in light of the '138 reference because that reference does not teach or describe the surprising result that the filtrate of oxidized hair contains biologically useful peptides, which are the compositions claimed in the present disclosure.

In response to this argument, applicants' attention is directed to the scope of the instant claims. The instant claims are directed to product by process, and all the elements of the claimed product are disclosed by US '138, which is composition comprising soluble peptide. US '138 further teaches low molecular weight peptides. The peptide disclosed by US '138 is soluble and used for cosmetics as desired by applicants. Therefore, the present product is identical of the product of US '138 and capable of functioning in the same way as a cosmetic. Therefore, claimed product by process is anticipated by US '138 because even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is anticipated even though the prior product

was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985). Since US '138 product is identical to the present claims, i.e. composition comprising water soluble peptide, the burden is shifted to applicants to show an obvious difference to prove that the prior art products do not necessarily or inherently possess the characteristics of the claimed product. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596(CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). Moreover, the instant specification fails to set forth any specific method by which the claimed peptides are obtained. Rather it provides a panoply of generalized conditions which embrace the teachings of the '138 patent. Therefore, absent a specific method which results in the claimed peptides it is anticipated that any method falling within the general teachings of applicant's specification will yield the claimed peptides.

It is further noted that applicants argue obviousness and unexpected results. Applicants' attention is directed to the present rejection that is an anticipatory rejection. In any event, regarding applicant's arguments of unexpected superior results in the instant specification, it is the examiner's position that the data in the specification regarding biologically active peptides in the filtrate are not unexpected results. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness...of the claims at issue." *In re Corkill*, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). *In Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results

are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon,* 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967).

C. Applicants argue that US '138 reference describes different proteins having high molecular weight, acid precipitable proteins. The present Specification discloses peptides of an average weight of 850 Daltons. In contrast, US '138 reference describes much larger peptides, the majority of which have a molecular weight of 25,000 to 67,000 Daltons. Even if the peptides of the present claims were contained within the composition with the larger peptides of the '138 preparation, there is no way to know that from reading the patent. There is also no suggestion in the patent that there is a low molecular weight fraction that could be isolated, or that any fraction of this preparation would have the cell growth activity of the claimed compositions.

In response to this argument, it is argued that US '138 at col.5, lines 22-25, and figure 1 disclosed that low molecular weight peptides are also produced. The methods of peptides separation and isolation according to their molecular weights are known in the art including different chromatography techniques, different electrophoresis techniques, and ultracentrifugation, as evident by "BIOCHEMISTERY" book by Voet et al., pages 75-107 (provided). According to the intended use of the peptide, the desired molecular weight would have been filtered and separated from the soluble peptides pool disclosed by US '138. Regarding the limitation of claim 55 that "90% of the water soluble peptide are between 300 and about 1300 Dalton in molecular weight", this

limitation is referring to the soluble peptides precipitated during the process of production, and it is not clear from the claim if the peptide included in the claimed composition are chosen from the 90% fraction having the molecular weight between 300 and 1300 Dalton, or chosen from the 10% having other molecular weights! This 90% fraction of soluble peptides having 300-1300 Dalton molecular weight is not claimed as the soluble peptides included in the claimed composition. Further, claim 55 recites “the precipitate comprises water soluble peptide”, and with this “comprising” recitation it is difficult to determine which fraction of peptide included in the claimed composition? Is it the 90% fraction having 300-1300 molecular weight or is it the 10% fraction having other molecular weights?

D. Applicants argue that neither US '138 render any claim obvious as it teaches away from the present claims. The '138 reference does not suggest that any useful fraction of peptides can be precipitated from a soluble preparation (i.e., isolated from the filtrate) of oxidized hair. The '138 does teach that a fraction can be precipitated by lowering the pH of the solution to below 4. Thus, the '138 reference teaches away from the present claims by teaching that the composition cannot be precipitated at pH above 4.5, and yet the claimed peptides are precipitated at neutral pH.

In response to this argument, it is argued that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of

course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994). Further, the disclosed examples and preferred embodiment do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). US '138 clearly teaches composition comprising soluble peptides, and the method of production of the composition does not impart patentability to the claims as previously discussed in this office action.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., pH above 4.5) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 55-56, 67, 68 and 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 15 of U.S. Patent No. 6,270,793. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and claims 1 and 15 of the issued patent are directed to composition comprising water soluble peptides. The process of making the water soluble peptides are not distinguishing to the claimed composition as discussed in section 5 of this office action.

9. Claims 55-65, 67, 68 and 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9-12, 20, 28-30 of U.S. Patent No. 6,274,155 (‘155) in view of US 5,276,138 (‘138). The present claims are directed to composition comprising water soluble peptide. Claims 1, 9-12, 20, 28-30 of US ‘155 are directed to composition comprising peptide. Although water soluble peptides are within the scope of the claims of US ‘155 and disclosed at col.7, lines 55-62, however, US ‘155 does not claim water soluble peptide. US ‘138 disclosed water soluble peptides that are suitable for cosmetic compositions as well as several

industrial compositions (col.4, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver composition comprising peptides as claimed by US '155, and replace the peptides with water soluble peptides disclosed by US '138, motivated by the teachings of US '138 that water soluble peptides are suitable for several uses including cosmetic composition and industrial composition, motivation would also arise from the desire of US '155 patent to include water soluble peptides in the disclosed composition, with reasonable expectation of having composition comprising water soluble peptides that have various uses in cosmetics and industry. The process of making the water soluble peptides are not distinguishing to the claimed composition as discussed in section 5 of this office action.

10. Claims 55-65, 67, 68, 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 13, 14, 27, 39, 40 of U.S. Patent No. 6,461,628. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and claims 1, 13, 14, 27, 39, 40 of the issued patent are directed to composition comprising water soluble peptides. The process of making the water soluble peptides are not distinguishing to the claimed composition as discussed in section 5 of this office action.

11. Claims 55-65, 67, 68 and 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, and 11 of U.S. Patent No. 6,544,548 ('548) in view of US 5,276,138 ('138). The present claims

are directed to composition comprising water soluble peptide. Claims 1, 10 and 11 of US '548 are directed to composition comprising peptide. Although water soluble peptides are within the scope of the claims of US '548 and disclosed at col.9, lines 10-14, however, US '548 does not claim water soluble peptide. US '138 disclosed water soluble peptides that are suitable for cosmetic compositions as well as several industrial compositions (col.4, lines 20-22). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver composition comprising peptides as claimed by US '548, and replace the peptides with water soluble peptides disclosed by US '138, motivated by the teachings of US '138 that water soluble peptides are suitable for several uses including cosmetic composition and industrial composition, motivation would also arise from the desire of US '548 patent to include water soluble peptides in the disclosed composition, with reasonable expectation of having composition comprising water soluble peptides that have various uses in cosmetics and industry. The process of making the water soluble peptides are not distinguishing to the claimed composition as discussed in section 5 of this office action

12. Claims 55-65, 67, 68, 93 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 7,001,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and claims 1-5 of the issued patent are directed to composition comprising water soluble peptides. The process of making

the water soluble peptides are not distinguishing to the claimed composition as discussed in section 5 of this office action.

Response to Arguments

13. With regard to the rejection of the claims 55-65, 67, 68 and 93 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of any of: US patent 6,270,793, US patent 6,274,255, US patent 6,461,628, US patent 6,6,544,548 and US patent 7,001,987, applicants have failed to provide terminal disclaimer or traverse the rejection and the response is considered to be acquiescence to the position taken by the examiner. The rejection is therefore repeated for reasons of record. See MPEP 37 CFR 1.111 (b).

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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